IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/542,506
Applicant	:	John L. Holahan
Filed	:	July 15, 2005
Title	:	Improved Thickened Beverages For Dysphagia
TC/A.U.	:	1618
Examiner	:	D. L. Jones
Conf. No.	:	5924
Docket No.	:	SITH 9317W1

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APPELLANT'S REPLY BRIEF (37 C.F.R. § 41.41)

This brief is in response to the Examiner's Answer dated November 23, 2010 and the Examiner's Corrected Answer dated December 7, 2010.

This brief contains these items under the following headings and in the order set forth below (37 C.F.R. § 41.37(c)(1)):

- A. THIS IDENTIFICATION PAGE
- B. STATUS OF CLAIMS
- C. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
- D. ARGUMENT
- E. CLAIMS APPENDIX

B. STATUS OF CLAIMS (37 C.F.R. § 41.37(c) (1) (iii))

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are: 89

B. STATUS OF ALL THE CLAIMS

1. Claims cancelled: 1-38 and 46-56

2. Claims withdrawn from consideration but not cancelled: 57-89

3. Claims pending: 39-45

4. Claims allowed: NONE

5. Claims rejected: 39-45

C. CLAIMS ON APPEAL

The claims on appeal are: Claims 39-45.

C. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R. § 41.37(c)(1)(vi))

The issues on appeal are:

- 1. Whether Claims 39-45, all of the claims under examination, are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
- 2. Whether Claims 39-45, all of the claims under examination, are properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.
- 3. Whether Claims 39-41 are anticipated by Wierlo, U.S. Patent 3,839,407 ("Wierlo") under 35 U.S.C. § 102(b).
- 4. Whether Claims 39-45, all of the claims under examination, are obvious under 35 U.S.C. § 103(a) over Applicant's Admission in view of *Wierlo* in further view of Uzuhashi et al, U.S. Patent No. 6,455,090 ("*Uzuhashi*").

D. ARGUMENT

This Reply Brief supplements but does not supersede Appellant's initial Brief filed August 10, 2010.

The Examiner's Answers do not raise any new ground of rejection pursuant to 37 CFR 41.39.

The Examiner's Answers repeat the final rejections without regard to Appellant's arguments. Appellant therefore repeats the arguments made in the brief filed August 31, 2010 by incorporating them herein by reference.

In addition to the arguments previously made, Appellant respectfully points out several flaws in the Examiner's Answer.

As discussed below, the Examiner has misconstrued the claims.

However, even as she construed them, the Examiner does not consider the prior art references in view of the claims.

Although the Examiner acknowledged that the claims include the limitation a dispensing machine that is capable of dispensing non-thickened beverages, she does not provide a cogent explanation as to how Wierlo dispenses non-thickened beverages. In fact, the Examiner admits at page 3 that "Wierlo discloses an apparatus for mixing thickened substances." Hence, Wierlo does not disclose or even suggest this limitation.

The Examiner's construction of the claims is flawed because she fails to recognize that the phrase from Claim 39, *suitable for consumption by a person suffering from dysphagia*, is a positive limitation and not merely a statement of intended use. The specification makes clear (e.g., the entire Background of the

Invention, ¶¶ [0002] – [0008]) that dysphagia is a clinical diagnosis and that persons suffering from dysphagia cannot reliably and comfortably swallow unthickened liquids like water, and the claims are unambiguously directed to a process for producing thickened liquids which are suitable for consumption by such persons. Appellant has previously submitted, in his initial Brief's discussion of resolving the level of ordinary skill in the pertinent art, that the person most concerned with preparation of beverages suitable for consumption by a person suffering from dysphagia would be a health care professional or a dietician involved in the care of such patients. The phrase "suitable for consumption by a person suffering from dysphagia" does have specific meaning to these artisans. Preparation and serving of such beverages is an everyday concern and occurrence. It would be obvious to them that items that melt – such as those disclosed by Wierlo – would not be suitable to serve to their patients. To those not skilled in the appropriate art these facts may not seem very obvious, but that is the point. Skilled artisans know exactly what the phrase does and does not mean. In this case, the preamble phrase, when read in the context of the entire claim, recites limitations of the claim and brings life and meaning to the claim as written.

Appellant has repeatedly relied on this limitation in the prosecution of the present application. For example, in Amendment C (response to first office action on merits), filed November 23, 2009, Appellant argued for patentability of Claim 39 because "those skilled in the art would immediately recognize that a milkshake (or other drink dependent on temperature to determine viscosity) melts

in the consumer's mouth and would therefore not be suitable for consumption by a person suffering from dysphagia." Even if the phrase "suitable for consumption by a person suffering from dysphagia" had not been clearly a limitation of the claim, this reliance on it would have transformed it into a limitation. MPEP §2111.02 cites with approval *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785 (Fed Cir. 2002): "[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention."

If the claims are properly interpreted and considered in view of the prior art, it is clear that Wierlo does not anticipate the claims. As previously explained, independent Claim 39 calls for a process for the production of homogenous single phase thickened beverages suitable for consumption by a person suffering from dysphagia, the process comprising connecting a source of aqueous liquid thickener to a dispensing machine that is capable of dispensing non-thickened beverages. Wierlo has none of the italicized elements of the process. Hence, the claims are allowable over Wierlo.

Moreover, the claims, as properly construed, are not obvious in view of Wierlo in combination with Uzuhashi et al or Appellant's commercial packets. The Examiner cannot establish *prima facie* obviousness. One of the requirements for *prima facie* obviousness is that all the claim limitations must be <u>taught</u> or <u>suggested</u> by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974), as cited in MPEP §2143.03 (2001 ed) (emphasis added). In this case, the *prima facie* case

fails, in part, because the cited references, in combination, do not teach or suggest all the claim limitations. The combination does not teach or suggest all the elements of independent Claim 39. For example, for reasons set forth above, the combination of references does not teach or suggest *connecting a source of aqueous liquid thickener* to a *dispensing machine that is capable of dispensing non-thickened beverages*.

If the claims are properly construed, the combination of references does not teach or suggest all the limitations of Claims 40-45, which depend from Claim 39, since they include all the limitations of Claim 39 and further define the invention.

The Examiner's position in regards to "new matter" in Claims 44 and 45, as set out at page 20 also is flawed. It is the Examiner's position that the range of constituents recited in the claim is not disclosed in the specification. The Examiner misapplies MPEP §2131.03, which relates to the content of prior art relied on to reject claims with limitations expressed in ranges. The Examiner's reasoning results in the anomalous situation where an applicant cannot limit the breadth of his own invention and is required to accept a broader scope of exclusivity than he has chosen if he is to get a claim allowed. In any event, Claim 44 provides for a process in accordance with Claim 42 where the xanthan gum is between 1% and 10% of the thickener concentrate. The specification, at ¶ [0053], states as follows: The amount of thickener employed in a concentrate thickener will depend greatly on the specific thickener chosen, its specific thickening properties, and the processing equipment employed. In general, the

amount employed will be an effective amount, such as between about 1 and about 10% thickener by weight. Hence, the limitations of Claim 44 are not new matter.

Likewise, Claim 45, calls for a process in accordance with Claim 42 where the xanthan gum is between 0.3% and 1% of the beverage. Original Claim 8 recites a treatment in accordance with claim 6 where the xanthan gum is between 0.1% and 3% of the final ready-to-consume liquid food. Hence, the limitations of Claim 45 were disclosed in the specification as filed and are not new matter.

Finally, at page 21 the Examiner mischaracterizes the teachings of ¶ [0054] of the specification when responding to Appellant's arguments regarding the term *aqueous liquid thickener*. Paragraph [0054] is not directed to a powder; it teaches one skilled in the art a method of making an aqueous liquid thickener by mixing a powder with water. More specifically, ¶ [0054] provides [t]he concentration may vary depending on the equipment and the thickener employed. In an aspect, a sufficient quantity of thickener powder for the concentrate thickener being prepared is admixed with water in a suitable mixing vessel. The specification confirms that the thickener is an aqueous liquid thickener in ¶ [0055]: the temperature of the water is not critical to the preparation of the concentrate thickener and may include, without limitation hot, cold, or room temperature water suitable for human consumption. One skilled in the art clearly would understand the meaning of the term aqueous liquid thickener.

The Examiner has failed to establish that Claims 39-45 are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, that they are properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention, or that they are unpatentable as obvious under 35 U.S.C. § 103(a) over Applicant's Admission in view of *Wierlo* in further view of *Uzuhashi*. The Examiner has also failed to establish that Claims 39-41 are anticipated by *Wierlo* under 35 U.S.C. § 102(b). Appellant has established that the Examiner erred in making the rejections. Appellant respectfully requests that these rejections of Claims 39-45 be reversed.

Date: <u>January 24, 2011</u> Respectfully submitted,

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E. CLAIMS APPENDIX (37 C.F.R. §41.37(c)(1)(viii))

- 39. A process for the production of homogenous single phase thickened beverages suitable for consumption by a person suffering from dysphagia, the process comprising connecting a source of aqueous liquid thickener to a dispensing machine that is capable of dispensing non-thickened beverages.
- 40. A process in accordance with Claim 39 wherein the dispensing machine includes a container of thickener concentrate, a switch which selectively controls whether or not the thickener concentrate is included in the beverage, and a metering pump and an in-line static mixer connected to the container of thickener concentrate and designed such that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not.
- 41. A process in accordance with Claim 39 wherein the dispensing machine includes a container of thickener concentrate, a switch which selectively controls whether or not the thickener concentrate is included in the beverage, a metering pump, and an exit nozzle, the exit nozzle producing a sufficient pressure drop that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not.
- 42. A process in accordance with Claim 39 wherein the thickener comprises at least one soluble food fiber thickener selected from the group consisting of

sodium alginate, potassium alginate, ammonium alginate, carrageenan, sodium carboxymethylcellulose, hydroxypropyl cellulose,hydroxypropyl methyl cellulose, locust bean gum, guar gum, and xanthan gum.

- 43. A process in accordance with Claim 42 where the thickener is xanthan gum.
- 44. A process in accordance with Claim 42 where the xanthan gum is between 1% and 10% of the thickener concentrate.
- 45. A process in accordance with Claim 42 where the xanthan gum is between 0.3% and 1% of the beverage.